AMREX®
electrotherapy equipment

May 08, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Reference: The Performance Standard for Electrode Lead Wires and Patient Cables

Citizen Petition

Attention: Jennie Butler,

The undersigned submits this petition under part 10.30 of Title 21 Code of Federal Regulations (CFR) to request the Commissioner of Food and Drugs to grant an exemption for Amrex-Zetron Inc. to part 898 of 21CFR.

Amrex-Zetron Inc. Patient Cables incorporate a banana style plug (diameter 0.150 inch minimum) which can not be plugged into and can not make conductive contact with an electrical (mains) socket or power cord. Compliance with the Performance Standard is unnecessary.

Amrex-Zetron Inc. Patient Cable's function and intended use is to provide an electrical shock to the patient. Contraindications, Warnings, and Precautions are included in all Amrex User's Guides. Refer to the attachments.

Environmental impact - Claim for categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.43 of this chapter or an environmental assessment under 25.40 of this chapter. Does not apply.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Paul K. Elliott

Paul K. Elliott
Manufacturing Manager
Attachments 2

PKE

a division of Amrex-Zetron, Inc.
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Web Site: http://www.amrex-zetron.com E-Mail: amrex@amrex-zetron.com

00P-1292

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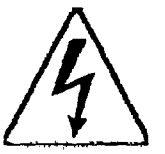
Contraindications—Warnings—Precautions

THIS INSTRUMENT OPERATES ON 120 VOLTS AC, 60 Hz. (unless otherwise indicated on the unit) AND MUST BE PROPERLY GROUNDED FOR SAFETY. The three wire power cord with "hospital grade" plug should be connected to a GROUNDED AC wall receptacle. It is the personal responsibility and obligation of the user to insure that this instrument is properly connected to the AC POWER source before use.

Warning–Risk of burns and fire. DO NOT use near conductive material such as metal bed parts or innerspring mattresses. Renew electrode cables upon evidence of deterioration. Use of controls, adjustment, or performance of procedures, other than those specified herein, may result in hazardous exposure to electrical energy.



Important

AMREX Intensity Reset Circuit: The Amrex Low Volt AC Muscle Stimulator incorporates a unique safety reset function as part of the intensity control. This is to prevent any sudden or inadvertent stimulation output to the patient in the event that:

- The Low Volt AC Intensity control is not set to the *0/Reset* position enabling the audible "click" at power on, provided the power has been off for more than ten seconds.
- The ac power is interrupted for more than ten seconds before power is restored.
- The treatment period has ended and more than ten seconds has elapsed before power on.

The Low Volt AC Intensity control must be returned to the *0/Reset* position enabling the audible "click" before stimulation output can be activated.

ATTACHMENT 1 of 2

Electrical Muscle Stimulation—Contraindications

- Contraindicated for patients with cardiac demand pacemakers.
- Should not be used on cancer patients.

Electrical Muscle Stimulation—Warnings

- Long term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of electrical muscle stimulation during pregnancy.
- Adequate precautions should be taken in the case of persons with suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
- Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
- Electrical muscle stimulators should not be applied transcerebrally.
- Electrical muscle stimulators should not be used over swollen, infected or inflamed areas or skin eruptions.
- Caution should be used in the transthoracic application of electrical muscle stimulators in that the introduction of electrical current into the heart may cause arrhythmias.
- Electrical muscle stimulators should be kept out of the reach of children.

Electrical Muscle Stimulation—Precautions

Precautions should be observed:

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Following recent surgical procedures when muscle contraction may disrupt the healing process.
- Over the menstruating uterus.
- Where sensory nerve damage is present by a loss of normal skin sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium. The irritation can usually be reduced by use of an alternate conductive medium or alternate electrode placement.

Skin irritation and burns beneath the electrodes have been reported with the use of electrical muscle stimulators.

ATTACHMENT 2 of 2